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Social and human rights questions: genetic privacy and non-discrimination

Information and comments received from Governments and relevant international organizations and functional commissions pursuant to Economic and Social Council resolution 2001/39

Report of the Secretary-General**

Summary

The present report includes information and comments received by one Member State and various entities of the United Nations system pursuant to Economic and Social Council resolution 2001/39 of 26 July 2001, entitled "Genetic privacy and non-discrimination". These comments and information highlight the potentials and dangers of new developments in the genetic field and refer to initiatives taken to provide a framework for ensuring respect for genetic privacy and non-discrimination, including the United Nations Educational, Scientific and Cultural Organization draft international declaration on human genetic data. The report concludes with recommendations on how the Economic and Social Council could proceed on this matter.

* E/2003/100.

** The present report is being submitted on 11 June 2003 in order to include as much information from United Nations entities as possible.

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I. Introduction

1. The Economic and Social Council considered the issue of genetic privacy and non-discrimination at its substantive session of 2001. In its resolution 2001/39 of 26 July 2001, the Council recognized and asserted the importance of the principle of non-discrimination on the basis of genetic characteristics. The Council urged States to ensure that this principle be respected and that genetic testing be done with the consent of the person concerned, while protecting his or her privacy. It also invited States to take appropriate specific measures to ensure respect for these principles, called upon them to promote the development and implementation of standards in this field and urged them to support research in the area of human genetics and biotechnology with due respect for the above-mentioned principles.

2. In addition, the Economic and Social Council requested the Secretary-General to bring resolution 2001/39 to the attention of all Governments and relevant international organizations and functional commissions in order to collect information and comments, and to submit a report thereon to the Council at its substantive session of 2003. The present report contains responses received by the Secretariat to a note verbale on the matter.

II. Information and comments provided by Member States

China

[Original: Chinese]

3. While the Government of China vigorously promotes research and development in the life sciences and biotechnology, it also attaches a high degree of importance to protecting genetic privacy, opposing genetic discrimination and strengthening the guidance and restraint exercised on scientific research by medical and biological ethics.

4. The Government of China conducts rigorous ethical reviews of medical research, especially scientific research involving the human subjects. Such ethical reviews centre on the selection of experimental subjects, respect for those subjects and informed consent. Such reviews make it possible to effectively protect the safety and privacy of experimental subjects and minimize the effects of scientific research on their physical and mental integrity and human dignity.

5. China has enacted a body of legislation that clearly regulates the development and use of genes and protects the right to privacy. The Pharmaceutical Administration Law and its implementing regulations established the procedures for the review and approval of the application of gene therapy techniques, while the Regulations on the Management of Human Genetic Resources contain provisions covering the import and export of human genetic material, international cooperation and so forth. The Government of China will soon promulgate the Measures for the Ethical Review of Biomedical Research Involving Human Subjects, with a view to further protecting the right to genetic privacy and preventing discrimination based on genetic problems.

6. As biotechnology continues to develop, the Government of China will continue to respond to new circumstances and problems and to safeguard the interests of the broad masses of the people by enacting and perfecting relevant legislation aimed at protecting genetic privacy rights and combating genetic discrimination.

III. Information and comments provided by the United Nations system

A. Commission on Science and Technology for Development

1. Introduction

7. The draft human genome map, which was unveiled in 2000, raised hopes for quick discovery of vaccines, drugs and tests to many human diseases and health conditions. It also raised fears about access, discrimination, ownership, equity and abuse of the genetic information. The power of genetic tools and the speed of discovery have increased the ability to profile individuals, specific populations, store, transmit and share their genetic data. As the tests and tools become common, simpler and accurate, generation of and access to genetic information of individuals and population increases and, with it, the chances of abuse of such data.

8. For example, about 4,000 health-related disorders have been attributed to genetic alteration caused by a single mutant gene. The Human Genome Project has identified many of such mutant genes. In fact, it is estimated that a new genetic alteration with some relations to health is discovered every day. Such information is very useful to public health planners, health caregivers, employers, insurers and educators but could also be used to discriminate against individuals and other third parties thought to be prone to specific conditions. Therefore, the need to respect individual rights and respect of privacy becomes a very important part in handling genetic information.

9. The person undertaking a genetic test is unlikely to be the only one interested in the results. Parents, children, spouses, siblings, health authorities, Governments, and insurers, among others, may be among those interested in such results for different motives.

10. Genetic information is important, not only in discovering new drugs, vaccines and tests, but also in promoting good health, health service planning (e.g., reducing exposure to risk factors) and enhancing national and global security. To realize many of these opportunities, investment in research and development has to be encouraged and protection of innovations promoted to provide sufficient incentives to the private sector. However, such incentives have to take into account the needs of developing countries, recognizing that the human genome is a common heritage and also recognizing the preservation of human dignity so that individuals are not viewed merely as genes. This requires balancing societal interests and individual privacy to achieve the promise of genomics to contribute to good health, global welfare and individual rights.

2. Contribution of the Commission on Science and Technology for Development

11. At its intersessional period of 1999-2001, the Commission on Science and Technology focused on national capacity in biotechnology and published studies that

included aspects of bioethics. The report on key issues in biotechnology concluded that biotechnology also gives rise to socio-economic and ethical concerns and that the policies and regulatory regimes intended to manage the risks depend largely on scientific capacity, including human expertise and well-equipped laboratories. This capacity simply does not exist in many developing countries at present.[1]

12. From different country reports addressed by the Commission, it is evident that bioethics is still in its infancy in many developing countries. While programmes to address biosafety have been promoted, bioethics has not received similar attention, except in the areas of health and medical research; but genomics extend beyond health. Even in health, the rights of patients and individuals in countries with limited health services, inadequate public awareness and limited financial strength are likely to be abused, especially when the legal and regulatory policies are not in place and public awareness is very low or absent.

13. It is recognized that the legal and regulatory regimes governing biotechnology, and genomics in particular, are still emerging, even in developed countries. These include biosafety, intellectual property rights and bioethics. Many developing countries, especially in Africa, are yet to enact legislation to promote the safe use, exploitation and protection of biotechnology tools, innovations and data. The Commission addressed public awareness and legal regulatory policies in developing countries and countries with economies in transition. This work revealed that legal and regulatory policies in biotechnology are either emerging or still being designed.[2]

3. Recommendations

14. There is a need for countries to address intellectual property rights, biosafety and bioethics with respect to collection, handling and storage of genetic data of individuals to promote human rights, dignity and privacy without stifling scientific, economic and social benefits or contribution of genomics to global well-being. This requires the involvement and participation of Governments, the private sector, public service providers and civil society. This could address the economic issues, such as investment in research and development, production and marketing of genetic products and information, as well as the protection and respect of intellectual property rights. It will also address the storage and flow of genetic data of individuals or populations among the relevant stakeholders. Specifically, the following areas require attention:

(a) Promotion of national policies for biotechnology regulation

15. This would involve working with relevant Government authorities, the private sector, academics, civil society and the public to develop policies on protection of individual privacy, encourage the research and development in genomics and eliminate or safeguard against discrimination based on genetic profile of individuals.

(b) Fair and equitable sharing of benefits accruing from genetic information

16. Biotechnology and genomics in particular rely heavily on the genetic materials isolated or collected from communities, individuals and environment possessing unique beneficial characteristics. Such information could become the basis of new remedies that could generate incomes. Therefore, it is important to develop mechanisms for equitable sharing of benefits arising from such genetic

characteristics. The aim is to encourage local communities to safeguard their genetic information and promote ethical standards and corporate responsibility.

(c) Raising public awareness on genetics and privacy

17. This is important in protecting individuals and societies from discrimination and abuse. Many of the problems of public perception and public awareness in genetic engineering in developed countries are relevant also in developing countries and countries with economies in transition. In many developing countries, there are also other significant difficulties in building public awareness. These include diverse levels of education and literacy across the country as a whole, and the inability for large parts of the population to access the mass media.

18. National Governments, international organizations and non-governmental organizations can play key roles in raising public awareness both by providing balanced information and by establishing and supporting public forums for open and transparent dialogue on the potential opportunities and challenges related to genetics and privacy.

(d) Scientific capacity-building

19. The scientific capacity of many developing countries is not well developed to handle emerging biotechnology-related issues. There is a need to promote strategic partnerships and alliances that could lead to quick transfer of information and technologies needed to manage the genetic revolution. This could include working with learning institutions, Governments and international agencies and the private sector to improve the scientific foundation.

4. Conclusion

20. Genetic information includes, but is not limited to, family history, physical characteristics (phenotype), biological sample and the sequences of genes, expressed or unexpressed (genotype). While recognizing that decoding the genetic information of individuals is a more powerful and accurate method of revealing the genetic secrets of individuals, its association with phenotypic characteristics makes all the other forms just as powerful. Therefore, all forms of genetic data require similar protection if the privacy of individuals is to be respected. For this to be achieved, public awareness and capacity-building efforts have to be increased. The involvement of all stakeholders with an interest in collection, analysis, storage, transmission and use of genetic materials and information is vital. Similarly, balancing protection of privacy with the need to realize the full potential of genomics requires the promotion of transparency in the handling of genetics.

B. Commission on Sustainable Development

21. The Commission has not considered in any focused manner the issue of genetic privacy and non-discrimination. However, the issue of biotechnology and transfer of technology, including the sharing of the advanced knowledge in human genome and its potential application to tropical infectious diseases, was discussed in panel discussions at the outset of the World Summit on Sustainable Development, held in Johannesburg and at the Science Forum, a parallel event held in Johannesburg. Participants stressed the need for disseminating human genome

information and the need for devoting more resources to research on tropical infectious diseases.

C. Office of the United Nations High Commissioner for Human Rights

22. The Commission on Human Rights has considered the issue of human rights and bioethics since 1991, in biannual resolutions starting with 1991/45 of 5 March 1991. In its most recent resolution (2003/Res.69), the Commission welcomed the initiative of the members of UNESCO to prepare an international declaration on human genetic data; urged States to take measures for the protection and confidentiality of personal genetic data concerning persons living or dead; in order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and international human rights law; and called upon States that had not yet done so to address the issue of discrimination arising from the application of genetics, in order to protect human rights, fundamental freedoms and dignity.

23. The Office of the United Nations High Commissioner for Human Rights (OHCHR) welcomes the strong human rights focus of the revised outline of the International Declaration on Human Genetic Data currently being considered by the International Bioethics Committee, which addresses, inter alia, the issues of concern to the Economic and Social Council raised in its resolution 2001/39.

24. During an expert consultation on human rights and biotechnology, convened by the High Commissioner for Human Rights in January 2002, the experts identified discrimination as one of three broad areas which should be of priority for the work of the High Commissioner and OHCHR. The conclusions of the experts were attached as an addendum to the report of the Secretary-General to the fifty-ninth session of the Commission on Human Rights on human rights and bioethics (E/CN.4/2003/98). The experts expressed a specific concern in two respects:

(a) The real possibility that an individual's existing genetic characteristics can be used as a basis for discrimination. This is of particular concern in relation to discrimination in employment and discrimination in the provision of insurance;

(b) The possibilities of genetic manipulation might eventually allow allegedly "undesirable" genetic traits to be progressively eliminated. This gives rise to concern about which genetic traits are so "undesirable" that their elimination should be encouraged or allowed. Additionally, the likely high cost of these procedures suggests that, initially at least, only those with sufficient resources may benefit from these procedures.

25. The experts noted that "while the exercise of an individual's right to health should in no way be limited by her or his genetic characteristics, in the sphere of employment and general insurance (including life assurance), genetic characteristics may sometimes be legitimately used to discriminate between individuals in relation to the availability and, if available, the costs of insurance." In this case, a human rights approach demands that the employer must demonstrate a legitimate occupational requirement and the insurer a clear increase in probability and risk of a claim justifying a refusal to insure or a higher premium. Regulation in this area is thus desirable for at least three reasons, namely:

- To prevent the application of genetic screening by state or non-State actors for illegitimate reasons or without the prior informed consent and pre/post test counselling of the person concerned
- To avoid discrimination based on perceptions rather than empirical data and rigorous risk assessment
- To avoid a situation in which individuals desist from submitting to genetic testing for fear that adverse results will be placed on their medical records and used as a basis of discriminating against them in the future, or that results are misconstrued and used as a basis for discrimination. The experts noted that the experience with HIV/AIDS was instructive in this regard.

26. A key aspect of genetic discrimination in employment and insurance is the storage and protection of genetic data, in particular the gradual accumulation of information on an individual's medical record which could in the future be used in a discriminatory way presently unforeseen. The experts felt that priority should be placed on promoting increased security of genetic data in order to (a) limit the risks of illegitimate discrimination and (b) encourage individuals to undergo genetic tests without fear that the information might be used to discriminate against them.

27. In paragraph 73 of the Programme of Action of the World Conference against Racism, Racial Discrimination, Xenophobia and Related Intolerance, held in Durban, South Africa[3] States were urged to take measures to prevent genetic research or its applications from being used to promote racism, racial discrimination, xenophobia and related intolerance, to protect the privacy of personal genetic information and to prevent such information from being used for discriminatory or racist purposes.

D. United Nations Educational, Scientific and Cultural Organization

1. The issues

28. Progress in genetic research continues to accelerate, opening up fresh possibilities of previously undreamed applications and posing new ethical problems. Genetic research clearly demonstrates that a person's genetic characteristic can cause or predispose him or her to many diseases, including those previously not thought to have a genetic component. The completion of the sequencing of the human genome announced in April 2003 has opened the way for far-reaching medical research and extensive biomedical applications, particularly with regard to medical diagnosis, prevention, epidemiological research, population genetics studies, etc. Furthermore, as each person's genetic heritage is unique, forensic science and the judicial system make use of it for identification purposes.

29. All these applications yield a considerable volume of processed and stored DNA sample or genetic data collections. This genetic data, whether collected for scientific, medical or other purposes, must be used judiciously, with respect for human rights, fundamental freedoms and human dignity.

30. Despite the existence of numerous declarations, guiding principles and codes dealing with the issue of genetic data, the changing conditions of genetic research call for the establishment of an international instrument that would enable States to

agree on ethical principles, which they would then have to transpose into their national legislation. These changes concern the increasing involvement of the private sector, the rapidly growing number of genetic databases, the controversial nature of certain of the intended applications (for example for insurance or employment purposes), the increasingly international nature of genetic research and the cross-border flow of genetic data.

2. The elaboration of an international declaration on human genetic data

31. The systematic study of the human genome, which began in the early 1980s as a result of unprecedented international scientific cooperation, as well as its foreseeable social, cultural and economic repercussions, were the reasons for which the United Nations Educational, Scientific and Cultural Organization (UNESCO) began to examine the accompanying ethical and legal issues. The adoption of the Universal Declaration on the Human Genome and Human Rights by the General Conference, unanimously and by acclamation, on 11 November 1997 at its twenty-ninth session, was the outcome of this initiative. One year later, on 9 December 1998, the General Assembly endorsed the Declaration, in its resolution 53/152.

32. Aware of the complexity and scale of the subject and also of the urgent need to define acknowledged principles and standards adopted at the international level, the Director-General of UNESCO asked the International Bioethics Committee to examine the possibility of drafting an international instrument on human genetic data. He announced his initiative to the Intergovernmental Bioethics Committee at its second session (held in Paris from 14 to 16 May 2001), which welcomed it. At its thirty-first session (held from 15 October to 3 November 2001), the General Conference of UNESCO, in its resolution 15 (31 C/Resolution 15), endorsed the proposal and requested the Director-General to keep it informed of the action which he intended to take on the advice and recommendations of the International Bioethics Committee and the Intergovernmental Bioethics Committee concerning the possibility of drafting an international instrument on genetic data.

33. Immediately following the thirty-first session of the General Conference and in regard to the reflection already undertaken by the International Bioethics Committee on genetic data, the Director-General entrusted it with the initial stages of the elaboration of an international instrument on genetic data. To this end, in 2002 the Committee set up an ad hoc drafting group that was invited to make any relevant proposals concerning the elaboration of the instrument. The group, made up of eminent members of the Committee and outside experts, is chaired jointly by Nicole Questiaux (France) and Patrick Robinson (Jamaica).

(a) On the substance

34. The preparation of an international declaration on human genetic data is a logical sequel of the Universal Declaration on the Human Genome and Human Rights (1997). Moreover, in its communiqué adopted on 23 October 2001, the Round Table of Ministers of Science on "Bioethics: international implications" expressed the view that possible extensions to the Universal Declaration on the Human Genome and Human Rights should be considered.

35. The draft declaration draws on the International Bioethics Committee reports entitled "Confidentiality and Genetic Data" (1999) and "Human Genetic Data: Preliminary Study of the IBC on its Collection, Processing, Storage and Use"

(2002), and is based on the work of the drafting group of the Committee which met in February, April, July and November 2002 and in February and April 2003. More generally, the declaration draws on all the reports drafted by the Committee since 1993. It will be recalled that the Committee dealt with the issue of human genetic data in its reports entitled "Genetic Screening and Testing" (1994), "Genetic Counselling" (1995), "Bioethics and Human Population Genetics Research" (1995), "Ethics and Neurosciences" (1995) and "Solidarity and International Cooperation between Developed and Developing Countries concerning the Human Genome" (2001).

(b) On the form

36. As to the form of the international instrument, from the very beginning the drafting group was clearly in favour of a non-binding instrument. After drawing up a comparative table of the merits of a declaration and a recommendation, it opted in favour of a declaration. The declaratory form is more appropriate to the formulation of principles that should subsequently guide States in the transposition into their domestic law in compliance with their own legal system and culture.

37. In this regard, the Executive Board of UNESCO, at its 165th session, held in October 2002, stated in paragraph 5 of its decision 3.4.2 (165 EX/Decision 3.4.2), that it was Aware at once of the complexity and the scope of the issue of genetic data and also of the urgent need to define in this regard principles and standards that are recognized and adopted at the international level. It therefore considered (in para. 8) that the Organization should prepare, as a matter of urgency, an international declaration on human genetic data with due regard for human dignity and human rights and freedoms.

38. The future declaration is organized on the basis of a statement of principles and standards, striking a balance between over-general prescriptions and over-precise ones that would only be appropriate to a binding instrument (such as a convention). In fact, the goal of a declaration is to give practical expression to a moral commitment, freely entered into by the community of States; the principles and standards it embodies can then guide the framing of national legislation and regulatory instruments, that can specify and define the prescriptions in detail in accordance with national legislative framework and legal traditions.

(c) On the content

39. The future declaration is intended to be founded on the fulcrum of universally recognized rights and freedoms, extending the Universal Declaration on the Human Genome and Human Rights and drawing on the existing body of principles and legal standards in the field of bioethics. A number of countries have enacted legislation, taken regulatory measures or adopted ethical standards relating specifically to human genetic data (in some instances) and, more generally, to medical data, personal data and sensitive data.

40. Furthermore, it takes into account the provisions adopted and reports drawn up by international organizations, in particular the United Nations, the International Labour Organization, the World Health Organization and UNESCO, and regional organizations, such as the Council of Europe, the Organisation for Economic Cooperation and Development and the European Union.

41. In addition, the draft international declaration makes a clear distinction between the various purposes for which human genetic data are collected and used on the one hand and, on the other, between the various stages of the collection, processing, storage and use of genetic data, despite the redundancy implicit in such distinctions with regard to the drafting of various articles. Therefore, the draft declaration respects this economy and follows this logic. Because the different phases in the handling of human genetic data raise different questions, the draft international declaration is clearly divided into sections that deal in succession with the collection, processing, use and storage of the data in question.

(d) International consultations

42. In accordance with UNESCO Executive Board 165 EX/Decision 3.4.2, a broad international written consultation on a revised outline of an international declaration on human genetic data (22 January 2003) was launched by UNESCO in February 2003. A questionnaire was prepared in order to gather any comments or suggestions concerning the revised outline. The questionnaire, together with a brief summary of the outline, was sent to all member States and associate members, to international organizations (the United Nations, its specialized agencies and more then 100 intergovernmental and non-governmental organizations), relevant national bodies (national ethics committees, commissions for the protection of privacy, universities, UNESCO bioethics chairs, etc.), and to some 150 specialists and personalities, including former members of the International Bioethics Committee. A number of representatives from the private sector, particularly the pharmaceutical industry, were also invited to take part in the international written consultation (all the documents concerning the consultation are available on the Internet: www.unesco.org/ibc).

43. Conscious of the importance of associating the main stakeholders with the drafting of the future declaration, the International Bioethics Committee furthermore decided to organize, on the occasion of the fifth meeting of the drafting group, a Public Hearings Day on human genetic data and the revised outline, which was held in Monte Carlo, Monaco on 28 February 2003. This Public Hearings Day brought together various groups particularly concerned by the proposed declaration (10 associations and institutions representing indigenous people, women, children, the disabled, patients, doctors and researchers, as well as the private sector and insurance companies).

3. Conclusions

44. The work undertaken by UNESCO in respect of genetic data, notably by the International Bioethics Committee with special reference to the drafting of an international declaration on human genetic data, has highlighted not only the complexity and scope of the question of genetic data, but also the urgent need to define principles and standards that are recognized and adopted at the international level, given the increasing use of such data for non-medical and sometimes ethically questionable purposes.

45. A first preliminary draft of the international declaration on human genetic data was examined by the International Bioethics Committee at its tenth session, held in Paris, from 12 to 14 May 2003. It includes the proposals made by the Committee at its ninth session, held in Montreal, Canada, from 26 to 28 November 2002, and the

observations formulated during the Public Hearings Day. In addition, it takes into account the comments made at the 166th session of the Executive Board of UNESCO (held at UNESCO House on 11 April 2003) and of the preliminary results of the written international consultation.

46. At its 166th session, held in April 2003, after having taken note of the work carried out by the International Bioethics Committee, particularly by the drafting group, the UNESCO Executive Board invited the Director-General to submit a consolidated text, taking account of the results of the international consultation, including the advice of the Committee at its May 2003 meeting, to a meeting of government experts (category II) responsible for finalizing the draft international declaration on human genetic data, which would be held at UNESCO headquarters in Paris, from 25 to 27, 28 or 29 June 2003), with a view to its adoption by the General Conference at its thirty-second session.

E. World Health Organization

47. The privacy of personal information is a fundamental tenet of health care, with roots as ancient as medicine itself. The obligation of physicians to keep confidential the information they obtain concerning their patients has been formally articulated since the time of Hippocrates and is recognized in the laws of member States of the World Health Organization (WHO). Failure to protect confidential information not only amounts to a breach of patients' trust in health-care providers, but undermines the entire health-care system. Patients who fear negative consequences from the disclosure of their private information may withhold facts that are essential for effective preventive, diagnostic, and therapeutic services or, worse yet, may refrain from seeking needed services. As recognized in Economic and Social Council resolution 2001/39, advances in genetic research have led to new means to prevent and treat diseases. But genetic technologies may also produce information, which, if revealed, can result in discrimination or other harm. Therefore, WHO commends the Economic and Social Council for its efforts to increase awareness of unauthorized genetic testing or disclosure of genetic information and to prohibit discrimination against individuals or groups based on genetic characteristics. WHO is pleased to provide information about its activities in this field, as well as comments on the issues presented.

48. Issues in genetic privacy and non-discrimination are matters of growing importance for WHO member States. As genetics becomes increasingly integrated into clinical medicine, reproductive decision-making and public health, genetic information will accumulate about the genomes of individuals and groups.[4] The right to privacy in genetic health entails more than just the confidentiality of one's genetic information. It also encompasses protection of bodily inviolability in the gathering of this information from individuals, protection regarding the ways genetic information about individuals and communities is used and by whom, freedom from discrimination or increased stigmatization based on genetic membership in a group or the possession of genetic "risk factors", particularly freedom from discrimination in access to social and economic benefits and the provision of health services.

49. Nonetheless, the issues of privacy and non-discrimination are not unique to genetics, but arise in health care generally and especially in predictive services (e.g.,

in HIV testing). Hence, professional, national and intergovernmental policies and principles regarding genetics must be framed with a clear understanding of their broader implications. At the same time, some special features of genetic information, for example, what it can reveal about family members, make it appropriate to pay special attention to protecting privacy and preventing discrimination in research and health services in this rapidly evolving field of biomedicine. Therefore, WHO has specially examined genetic privacy and non-discrimination in recent years, for example in reports such as *Genomics and World Health* and *Review of Ethical Issues in Medical Genetics*.[5] Likewise, the rights to health,[6] to privacy,[7] and to non-discriminatory treatment,[8] which are embodied in the WHO Constitution and other international human rights documents, as well as in the constitutions of many WHO member States, are of great relevance to Economic and Social Council resolution 2001/39.

50. Accordingly, the WHO Research Policy and Cooperation Department, Human Genetics Programme, Ethics and Health Unit, Human Rights Team, Reproductive Health and Research, Disability and Rehabilitation Team, Traditional Medicines, and Gender and Women's Health Department have identified a number of relevant genetic privacy and non-discrimination issues that deserve the attention of the Council. The consolidated remarks which follow outline some of the key findings documented in the reports and studies carried out by WHO, as well as additional information that amplifies our perspectives in this matter. We have distilled our conclusions into five core issues concerning privacy, confidentiality and non-discrimination as they relate to the duties of biomedical professionals (genetic researchers) to patients and subjects and the obligations of States to promote and protect relevant human rights.

1. Confidentiality and control over one's genetic information

51. Since genetic information is obtained based on the voluntary, informed consent of a patient or a research subject, this person should typically control who has access to the information. Health-care professionals usually promise (explicitly or implicitly) that genetic data, like other medical information, will be treated confidentially. However, both privacy and confidentiality can be limited by consent or by the just claims of others with due process. While it would be wrong to seek a patient's or subject's consent for an unethical act (such as indiscriminate release of genetic data), it is often appropriate to ask for and obtain consent to set limits on confidentiality or even to waive it entirely.

52. In other instances, the social importance of research may justify using genetic samples for scientific studies without express consent, although usually only in an anonymous fashion so that the results cannot be linked to a particular person but used only for population reasons. Professional guidelines and regulations or legislation provide means of ensuring that all exceptions to the requirement of informed, voluntary consent are invoked only in appropriate situations and with due attention to the rights and well-being of the persons involved.

53. A more complex issue arises when genetic information about one person is shared with relatives for whom the information could have important health consequences. As the Advisory Committee on Health Research observed, genetic information about a specific health or reproductive risk of a particular individual will often imply a similar risk for other family members. In cases of relatively

isolated groups, which are unusually genetically homogenous, information about individuals may have implications about the wider group, not just other immediate family members.[9] Generally, the Advisory Committee contends that health considerations, rather than reproductive choices of other persons, may justify limits to confidentiality. Providing the information to family members will typically not harm the patient as the information is equally about the family member who consequently has a comparable interest in obtaining it, and confidentiality need not be promised to patients in these circumstances. In such situations, patients can have a moral obligation to provide the information to potentially affected family members, and many believe that it should be permissible at least in some cases for health-care providers to do so as well, without the consent of the patient, if necessary.[9]

54. Nevertheless, there may be special circumstances, either individual or cultural, that may warrant not giving information to affected family members in particular cases, for example, if doing so will likely lead to harm or violence to the individual.[10] For that reason, the elaboration and application of ethically justified limits to genetic privacy requires institutional structures and processes to evaluate the circumstances and consequences of any exception to confidentiality without an individual's consent.

55. Furthermore, a human rights approach to health requires that limitations of certain rights on public health grounds must be justified under narrowly defined circumstances. Under the Siracusa principles of international human rights law, governmental limitations on the exercise or enjoyment of a right must be closely scrutinized, regardless of the apparent importance of the public good involved. It must be clear that the human right in question (here, the right of privacy) is one which can be limited, and the limitations must be necessary (both regarding the end in question and the absence of other, less intrusive means), and they must not be imposed in an arbitrary or discriminatory manner. This underlines the importance of Member States ensuring that they have honoured their human rights obligations at every stage of developing, monitoring, and implementing genetic screening and testing programmes.

2. Freedom from genetic discrimination

56. The predictive power of genetic testing and screening can be valuable to persons in many ways — from making reproductive decisions to planning career or other life choices — especially when neither prevention or therapy yet exists. However, this predictive power can also result in discrimination against, or stigmatization of individuals in many contexts and hence have grave consequences in terms of health and well-being. People are obviously not "responsible" for their own genetic constitution (genome) and it thus seems unfair to penalize them for the health risks that flow from this source — that is, we are not responsible for our good or bad luck in the "genetic lottery." This sense underlies the widely held view that discrimination according to genetic risks or characteristics in employment or health insurance is not justified. While worries arise everywhere about genetic discrimination, the Advisory Committee found them to be particularly acute in developing countries where they can be expected to increase as genetic services become more available.[10]

57. Unlike current health problems that are severe enough to prevent a person from carrying out particular employment even when reasonable accommodations have been made for his or her disabilities, genetic risks for future health problems should not be used to bar otherwise qualified persons from employment, and sanctions should be appropriately imposed on employers who act unethically.[11]

58. Similar issues arise regarding insurance, especially as the shift from public to private control of health insurance leads to greater reliance on health risk indicators, including genetic risks, in insurance underwriting.[12] "As a wider range of genetic tests become available and their cost continues to decline, the incentives and abilities of insurers to use this information to discriminate against individuals with risks of developing serious disease will increase."[10] Countries without adequate safeguards for non-discrimination may be particularly at risk. Thus, countries struggling to meet the health-care needs and services for their populations should implement safeguards to ensure the protection of the right to privacy and non-discrimination based on genetic health information, prior to the broad introduction of genetic services.

59. These ethical concerns regarding unjust discrimination are mirrored in the principle of freedom from discrimination guaranteed by human rights law. Governmental responsibility for non-discrimination includes ensuring equal protection and opportunity under the law, as well as de facto enjoyment of rights, such as the right to public health, medical care, social security and social services. The prohibition of discrimination does not mean that differences should not be acknowledged, only that different treatment (that is, the failure to treat cases) must be based on just and reasonable criteria.

60. Genetic screening (or the failure to screen for genetic conditions) can affect the amount and quality of information one has about his or her health advantages or risks. Genetic discrimination therefore encompasses not merely the harm that occurs from the misuse (or unconsented use) of personal genetic data, but also from unjustified barriers to access to genetic services.

61. The right to health enunciated in the WHO constitution has been firmly endorsed in a wide range of regional and international human rights instruments.[13] Most recently and authoritatively, it has been elaborated on by General Comment 14, adopted in May 2000 by the Committee on Economic, Social and Cultural Rights, which monitors the implementation of the International Covenant on Economic, Social and Cultural Rights.[14] The Committee holds that the right to health contains four interrelated and essential elements — availability, accessibility, acceptability, and quality — the precise application of which will depend on the conditions prevailing in a particular State party. Regarding the second element, the Comment states that health facilities and services "have to be accessible to everyone without discrimination, within the jurisdiction of the State party". Of particular relevance to the issue of genetic discrimination are several dimensions of accessibility:

- Non-discrimination: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population, in law and in fact, without discrimination on any of the prohibited grounds.
- Information accessibility: accessibility includes the right to seek, receive and impart information and ideas concerning health issues. However, accessibility

of information should not impair the right to have personal health data treated with confidentiality.

62. Finally, as recognized in the role accorded to civil society in the Economic and Social Council resolution, we note that non-governmental organizations can play an important role in disseminating information about human rights and ethical safeguards to policy makers, patients, and health-caregivers. In this regard, special consideration should be given to the issues of genetic privacy and non-discrimination in developing countries.

3. Privacy and traditional genetic resources

63. Privacy extends to the genetic resources of traditional knowledge. We share the "concern that traditional knowledge is sometimes appropriated, adapted and patented by scientists and industry, from the most part from developing countries, with little or no compensation to the custodians of this knowledge and without their prior informed consent".[15] While the issue of "biopiracy"[16] of traditional medicine extends beyond the usual understanding of genetic privacy, it is appropriate to apply to the context of communal integrity and control over genetic resources, the concerns for individual welfare that justify the right of privacy in ethical terms, just as human rights instruments now insist on appropriate measures to safeguard the property of indigenous peoples.

4. Non-discrimination and disability rights

64. Some disability rights groups have challenged the use of genetic screening for certain conditions (particularly in the context of preconceptual or prenatal tests) on the grounds that this practice contributes to discrimination against persons who have those conditions. Decisions about what conditions justify genetic testing are based on normative judgements about what is healthy or unhealthy, "normal" or "defective." Disability advocates argue that the disadvantages of disability stem from society's failure to accommodate disabled persons, prejudices and stereotypes about disabled persons, and discriminatory judgements about what constitutes a "good life", not supported by the social scientific data on the experience of being disabled or raising a disabled child.[17] Knowing in advance one's genetic health status will not determine whether one will lead a good life. Moreover, "disabled persons have made many positive contributions to the lives of others and to society. Finally, some worry that genetic screening and testing are part of broader, undesirable pressures towards normalization, conformity, and intolerance of difference."[18] Disability rights groups argue that, while a few genetic disorders, such as Lesch-Nyhan or Tay-Sachs disease, are extremely severe, what is truly limiting about disability is the discriminatory perceptions of persons in societies.

65. The Advisory Committee on Health Research concluded that Member States needed to consider the disability rights critique as part of their efforts to overcome discrimination. As noted above, freedom from discrimination in relation to health is extending to new grounds, including health status, physical and mental disability. There is also a move to develop a convention on the rights of persons with physical and mental disabilities, which will elaborate Government obligations to promote and protect the human rights of persons with disabilities in line with concerns outlined above from disability rights groups. WHO supports the development of this convention.

5. Gender, privacy and non-discrimination

66. Freedom from discrimination on the basis of sex and gender roles permeates all matters concerning health and intersects with other grounds of non-discrimination, as well as with other human rights, such as the right to privacy discussed above. In particular, predictive testing and health information can be withheld or used in ways that are deeply prejudicial to people, particularly to women. Genetic testing and screening programmes should offer awareness and counselling programmes that sensitize health-caregivers to the complexities of decision-making on genetic health issues and support the needs and interests of persons to make their own decisions.[19]

67. In countries (especially low-resource ones) where abortion services are not available or are prohibited by law, genetic testing programmes can be harmful to women who lack the means to act safely on the information obtained.[20] Moreover, even when such services are available, women need to be provided with fair and accurate information about their choices and the reliability of genetic tests and screening methods. The goal should be to discuss with, rather than simply inform, women — and their partners if women wish to involve them — the utility, accuracy, and consequences of genetic screening in terms of the potential results, the options for action that will be available, and to empower women to make non-coerced choices.[21]

68. Furthermore, genetic information can be used to discriminate or stigmatize women in the context of other social practices, such as a social or cultural preference for sons.[21] For example, prenatal genetic tests have been used as a means to carry out sex selection and thus prevent the birth of female babies. A stable sex ratio is a public good.[22] Governments and other organizations should undertake an assessment of special risks from potential disclosure of genetic information before genetic research, screening, and testing goes forward, in order to limit harms to women.[23] Moreover, genetic services need to be accompanied by public education strategies that effectively redress deep-seated, entrenched beliefs and values in societies that subordinate or devalue women.[24] This is consonant with the United Nations Millennium Development Goals and the Convention on the Elimination of All Forms of Discrimination against Women. Thus, the Council should consider specific gender considerations in its resolution on genetic privacy and non-discrimination.

IV. Conclusion and recommendations

69. **The views presented in the present report testify to the importance and the complexity of genetic privacy related issues. In this context, international efforts to ensure non-discrimination on genetic grounds would clearly need to be pursued, as much as the need to assist countries, particularly developing countries, in taking advantage of genetics, biotechnologies and other related scientific progress in their development process, in due respect for all human rights.**

70. **The UNESCO draft international declaration on human genetic data covers important ground on genetic privacy and non-discrimination. The Council may wish to be kept informed of developments in the elaboration of this instrument. It may also wish to continue considering the various**

implications of this question on ethical, legal, medical, employment related and other aspects of social life, and to advocate for assistance to be provided to countries in need to better deal with these issues.

71. In view of the limited number of views received thus far by Member States, the Council may wish to invite them to provide information and comments as a follow-up to Economic and Social Council resolution 2001/39 and on the present report, which covers the views of major United Nations entities involved in the matter. The Council could then, at its substantive session of 2004, consider the issue with a clearer picture of the views of Member States and more comprehensive information.

Notes

[1] UNCTAD (2002), *Key issues in biotechnology*, UNCTAD/ITE/TEB/10. The report can be downloaded from http://www.unctad.org/stdev.

[2] Summary report by the UNCTAD Secretariat of the Panel on Legal Regulatory Issues in Biotechnology of the Commission on Science and Technology for Development, document E/CN.16/2001/Misc.2.

[3] See A/CONF.189/12 and Corr.1, chap. I.

[4] Advisory Committee on Health Research. *Genomics and World Health* (p. 155). World Health Organization: Geneva, 2002. (Hereinafter, *Genomics and World Health*.) The report is on the agenda for consideration by the WHO Executive Board at its next meeting in May of 2003.

[5] Wertz, D. C., J. C. Fletcher, and K. Berg. *Review of Ethical Issues in Medical Genetics: Report of Consultants to WHO*. World Health Organization: Geneva, 2001. WHO/HGN/ETH/00.4 (Hereinafter *Review*).

[6] The "right to health" is expressed in the Preamble to the WHO Constitution (1946), which describes "the enjoyment of the highest attainable standard of health" as "one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition".

[7] See article 12 of the *Universal Declaration of Human Rights*, 1948.

[8] In relation to health and health care, the grounds for non-discrimination have evolved and can now be summarized with reference to the right to the highest attainable standard of health as proscribing "any discrimination in access to health care and the underlying determinants of health, as well as to means and entitlements for their procurement, on the grounds of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, health status (including HIV/AIDS), sexual orientation, civil, political, social or other status, which has the intention or effect of nullifying or impairing the equal enjoyment or exercise of the right to health". General Comment 14 on the right to health, adopted by the Committee on Economic, Social and Cultural Rights on 11 May 2000, paragraph 18 (see E/C.12/2000/4).

[9] *Genomics and World Health*, p. 156.

[10] Ibid., p. 157.

[11] Ibid., p. 159.

[12] We take the mention of "medical insurance" in the penultimate preambular paragraph of resolution 2001/39 to encompass all forms of insurance coverage for health-related services, not merely medical care.

[13] See the Universal Declaration of Human Rights (article 25 (1)), the International Covenant on Economic, Social and Cultural Rights (article 12), the International Convention on the

Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination against Women, the Convention on the Rights of the Child, the European Social Charter, the African Charter on Human and Peoples' Rights, the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights. Similarly, the right to health has been proclaimed by the Commission on Human Rights and further elaborated on in the Vienna Declaration and Programme of Action of 1993 and other international instruments.

[14] General comments serve to clarify the nature and content of individual rights and to clarify States parties' obligations.

[15] World Health Organization. *Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine*, Bangkok, 6-8 December 2000, p. 5.

[16] The word biopiracy refers to the attempt of individuals, groups or companies to patent biological materials native to developing countries, without consent, consultation, or compensation, especially when the information is obtained through deception, coercion and exploitation. To combat this problem, China and India now require official authorization prior to the removal of human genetic material.

[17] Parens, Erik and Adrienne Asch (eds.). *Prenatal Testing and Disability Rights*. Georgetown University Press, 2000; *Genomics and World Health*, p. 165.

[18] *Genomics and World Health*, pp. 165-166.

[19] *Review*, pp. 20-22.

[20] *Genomics and World Health*, p. 161.

[21] *Review*, p. 6.

[22] *Genomics and World Health*, p. 161.

[23] Ibid., p. 160.

[24] *Genomics and World Health*, p. 162; *Review*, pp. 16-20.